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The time period for reply, if any, is set in the attached communication.

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**BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number: 10/664,004
Filing Date: September 16, 2003
Appellant(s): BURKETT ET AL.

John S. Nagy
<u>For Appellant</u>

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed October 14, 2010 appealing from the Office action mailed May 28, 2010.

**(1) Real Party in Interest**

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The following is a list of claims that are rejected and pending in the application:

1-3, 6, 7, 10-17, and 31

**(4) Status of Amendments After Final**

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

**(5) Summary of Claimed Subject Matter**

The examiner has no comment on the summary of claimed subject matter contained in the brief.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

**(7) Claims Appendix**

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

**(8) Evidence Relied Upon**

| | | |
|---|---|---|
| US 2004/0010189 A1 | van Sloun et al. | 1-2004 |
| US 6,296,616 | McMahon | 10-2001 |
| US 2004/0039309 A1 | Murayama et al. | 2-2004 |
| US 6,033.720 | Stoltze et al. | 3-2000 |
| US 6,251,085 | Tezuka | 6-2001 |
| US 5,228,453 | Sepetka | 7-1993 |
| US 5,443,907 | Slaikeu et al. | 8-1995 |

### (9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

**Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 6, 10, 11, 13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by van Sloun et al. (US 2004/0010189 A1).

With regard to claim 1, van Sloun et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal core section and a distal core section having a tapered distal end (Fig. 1 tapering region indicated at 9); wherein at least a section of the elongated wire core includes at least one of randomized and non-randomized tactile surface contours (Fig. 1 provided by member 6); an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non- randomized tactile surface contours for at least a portion of the elongated wire core including at least a portion of the tapered distal end and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated wire core (Fig. 1 coating 7); and a flexible tubular member disposed over the distal core section (Fig. 1 member 6).

With regard to claims 3, 6, 10, and 11, see contours provided by 6.

With regard to claim 13, see flexible member 6 and coating 7.

With regard to claim 15, the coating is Teflon ([0021]).

## Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Sloun et al. (US 2004/0010189 A1) as applied to claim 1 above, and further in view of McMahon (U.S. Patent 6,296,616).

With regard to claim 2, van Sloun et al. teach an intraluminal guide wire substantially as claimed. Van Sloun et al. do not teach the size of member 6. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of van Sloun et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art,

discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 7, van Sloun et al. teach an intraluminal guide wire substantially as claimed. Van Sloun et al. do not disclose the size of member 6. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the number of contours and thus the spacing of the contours to place it within a range of .05 cm to 2 cm because it would serve as a means to adjust the surface contact area and thus the friction to achieve a desired amount of frictional resistance. Further, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). The peaks of the contact regions have a spacing of .005 cm to .5 cm (Col. 2 lines 57-58) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of van Sloun et al., with a spacing of about .05 to 2 cm as McMahon discloses an overlapping range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Sloun et al. (US 2004/0010189 A1) as applied to claim 1 above, and further in view of Murayama et al. (US 2004/0039309 A1).

With regard to claim 14, van Sloun et al. teach a guide wire substantially as claimed. Van Sloun et al. do not disclose the material of the guide wire. However, Murayama et al. teaches a guide wire with two different sections (Fig. 7 sections 2 and 3). The two sections are made from different alloys (Pg. 4 [0070]), the distal section (Fig. 7 section 2) is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section (Fig. 7 section 3) is made from a stainless steel (Pg. 4 [0071]). This provides the catheter with a high pushability and a high torque transmission which enhances operationality and improves trackability ([0070]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the guide wire in van Slounet al. out of steel and a nickel-titanium alloy because Murayama et al. teach this to enhance guide wire performance.

6. Claims 1-3, 6, 7, 10, 11, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720) in view of McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), and Sepetka (US 5,228,453).

With regard to claim 1, Stoltze et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal core section and a distal core section having a tapered distal end (Fig. 3 core 10a); and an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the surface for at least a portion of the elongated wire core including at least a portion of the tapered distal end and having a surface contour that follows the surface in the elongated wire core (Fig. 3 coating 17). Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the

movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3 lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

With regard to claim 2, Stolze et al. does not teach surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Stolze et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it

has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 3, 6, 7, 10, and 11, see contours in McMahon and Tezuka.

With regard to claim 14, the proximal section is formed of stainless steel and the distal portion is formed of a titanium nickel alloy (Col. 3 lines 66-67, Col. 4 lines 14-18).

With regard to claim 15, see Col. 4 lines 56-57.

With regard to claim 16, Stolze et al. teach an intraluminal guide wire, comprising: an elongated core having a proximal core section and a distal core section including a taper transitioning to a distal end (Fig. 3 core 10a); and a polymer coating of generally non-uniform thickness adhering without a gap to at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core (Fig. 3 see coating 17). Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for

reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3 lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

With regard to claim 17, see contours in McMahon and Tezuka.

7. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720), McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), and Sepetka (US 5,228,453) as applied to claim 1 above, and further in view of Slaikeu et al. (US 5,443,907).

With regard to claims 12 and 13, Stolze et al. and Sepetka teach a guide wire substantially as claimed. Stolze et al. and Sepetka do not teach the coating to be disposed under or over the flexible member. However, Slaikeu et al. teach a flexible member which is encased in a polymer coating the coating provides a low friction coating (Col. 5 lines 29-35, Col. 7 lines 1-4) while the flexible member provides radiopacity (Col. 8 lines 46-61). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to surround the flexible member with the polymeric coating in Stoltze et al. and Sepetka as in Slaikeu et al. because this allows for the guide wire to be viewed with fluoroscopy while maintaining low friction for ease of maneuverability.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720) in view of McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), Sepetka (US 5,228,453), and Slaikeu et al. (US 5,443,907).

With regard to claim 31, Stoltze et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal wire core section and a distal wire core section including a taper transitioning to a distal end (Fig. 3 core 10a); a polymer coating of generally non-uniform thickness adhering to and contiguous with at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core (Fig. 3 coating 17), the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy (Col. 3 lines 66-67, Col. 4 lines 14-18); and the polymer coating includes a fluoropolymer (Col. 4 lines 56-57).

Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a

flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3 lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

Stolze et al. does not teach surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Stolze et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Stolze et al. and Sepetka do not teach the coating to be disposed under the flexible member. However, Slaikeu et al. teach a flexible member which is encased in a polymer coating the coating provides a low friction coating (Col. 5 lines 29-35, Col. 7 lines 1-4) while the flexible member provides radiopacity (Col. 8 lines 46-61). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to surround the flexible member with the polymeric coating in Stoltze et al. and Sepetka as in Slaikeu et al. because this allows for the

guide wire to be viewed with fluoroscopy while maintaining low friction for ease of maneuverability.

**(10) Response to Argument**

**Ground I Rejection of the Claims Based on the van Sloun et al. Reference**

With regards to Applicant's arguments with respect to van Sloun et al., Applicant has argued that van Sloun et al. do not teach the coating to adhere to and be contiguous with the wire core. The Examiner finds that the claim recites the coating adheres to and is contiguous with the contours for a portion of the core (emphasis added), the claim does not explicitly recite that the coating adheres to and is contiguous with the core. However, the Examiner finds that the coating adheres to and is contiguous with the contours as shown in Figure 1 and would also adhere to and be contiguous with the core via the contours provided by the coil. The Examiner finds the counters of van Sloun et al. to be at least non-randomized. The claim recites the wire core includes at least one of randomized and non-randomized contours (emphasis added).

**Ground II Rejection of the Claims Based on the Stoltze et al., McMahon, Tezuka, and Sepetka Patents**

With regard to Applicant's arguments with regard to Stoltze et al., McMahon, and Tezuka, Applicant first argues there is no motivation to combine because Stoltze et al. already has a low friction coating. The Examiner finds that by reducing the contact surface area of the wire of Stoltze et al. as in McMahon and Tezuka additional friction reducing benefit can be had. Both Tezuka (Col. 5 lines 45-46) and McMahon (Col. 3 lines 65-67) also use low friction lubricants on their surface as well as having a reduced contact area to provide additional

reduction in friction. Though Stoltze et al. may teach that a grinding process is used on the coating, the Examiner does not find this to explicitly teach away from adding surface contours to reduce the surface contact areas. Applicant further argues that the references to not disclose randomized surface contours. The Examiner does not find that Applicant has provided any special definition or claim limitations which disclose in what way or to what degree the surface contours must be, for example, ordered or disordered, alike or different, to be considered randomized or non-randomized. The Examiner finds that Tezuka shows that the surface contours can be of varied sizes and teaches that the projections may vary depending on the user's desired shape (Col. 5 lines 5-8) and McMahon teaches maintaining a constant outer diameter by having a coating of non-uniform thickness. The Examiner finds Tezuka to teach "randomized" surface contours.

**Ground III**

See the Examiners response to Ground II above.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Emily Schmidt/

Examiner, Art Unit 3767

Conferees:

/LoAn H. Thanh/ for SPE Kevin Sirmons

Supervisory Patent Examiner, Art Unit 3764

/Sue Lao/

Primary Examiner